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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,792	02/27/2004	Deepa Eveleigh	5152	8120

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EXAMINER

SCHLAPKOHL, WALTER

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/788,792	Applicant(s) EVELEIGH ET AL.	
	Examiner Walter Schlapkohl	Art Unit 1636	<i>WLF</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2 and 5, drawn to methods for providing a patient diagnosis and methods for distinguishing between normal and disease tissues comprising comparing the level of expression of one or more **genes** in a first biological sample with one or more **genes** in a second biological sample as the claims read on one or one combination of genes selected from SEQ ID NOS: 1-127, classified in class 435, subclass 6.
- II. Claims 3 and 6, drawn to methods for providing a patient diagnosis and methods for distinguishing between normal and disease tissues comprising comparing the level of expression of one or more **gene products** in a first biological sample with one or more **gene products** in a second biological sample as the claims read on one or one combination of genes selected from SEQ ID NOS: 128-254, classified in class 435, subclass 7.1.

Art Unit: 1636

III. Claims 8 and 11, drawn to methods for monitoring the response of a patient being treated for breast cancer with an anti-cancer agent and methods for identifying a compound useful for the treatment of breast cancer comprising analyzing the level of expression of one or more **genes** in a sample prior to treatment with a compound and the level of expression of one or more **genes** in a sample after treatment with a compound as the claims read on one or one combination of genes selected from SEQ ID NOS: 1-127, classified in class 435, subclass 6.

IV. Claims 9 and 12, drawn to methods for monitoring the response of a patient being treated for breast cancer with an anti-cancer agent and methods for identifying a compound useful for the treatment of breast cancer comprising analyzing the level of expression of one or more **gene products** in a sample prior to treatment with a compound and the level of expression of one or more **gene products** in a sample after treatment with a compound as the claims read on one or one combination of genes selected from SEQ ID NOS: 128-254, classified in class 435, subclass 7.1.

Art Unit: 1636

V. Claim 13, drawn to an array comprising one combination of **genes** selected from SEQ ID NOS: 1-127, classified in class 435, subclass 287.2.

VI. Claim 14, drawn to an array comprising one combination of **gene products** selected from SEQ ID NOS: 128-254, classified in class 435, subclass 287.1.

The inventions are distinct, each from the other, for the following reasons:

Groups I-VI are comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different polynucleotides/polypeptides which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific polynucleotide/polypeptide combination to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the polynucleotides/polypeptides are different and distinct and thus the methods drawn to different and distinct polynucleotides/polypeptides are different and distinct inventions from each other.

Art Unit: 1636

Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to independent or distinct combinations of polynucleotides and polypeptides, followed by an election of a single invention drawn to one combination of polynucleotides or polypeptides within the elected multi-invention group, was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention drawn to each separate sequence which would require a much longer communication.

For related process inventions, the inventions are distinct if (a) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; (b) the inventions as claimed are not obvious variants; and (c) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function or effect. See MPEP § 802.01.

The methods of Groups I & III and Groups II & IV do not overlap in scope because the Group I & III inventions comprise methods comparing expression profiles of polynucleotide genes and the Group II & IV inventions comprise comparing expression profiles of polypeptide gene products. Thus, the Group I & III

Art Unit: 1636

and Group II & IV inventions have a materially different design, mode of operation and/or effect since the Group I and III profiles to be compared utilize nucleic acids which are chemically and structurally different from the Group II & IV profiles. Moreover the Group I & III and Group II & IV inventions are not obvious variants because, for example, the nucleic acid expression profiles of the Group I & II inventions do not necessarily correlate with the polypeptide expression profiles as in the Group II & Group IV inventions. Therefore, the methods are not obvious variants over each other.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The methods of Groups I-II and Groups III-IV do not overlap in scope because the Group I-II inventions comprise methods for providing a patient diagnosis and for distinguishing between normal and diseased tissue while the Group III-IV inventions

Art Unit: 1636

comprise methods for monitoring the response of a patient being treated for breast cancer with an anti-cancer agent and methods for identifying a compound useful for the treatment of breast cancer. The Group I-II and Group III-IV inventions have a materially different design, mode of operation and/or effect since the Group I-II inventions comprise comparing the expression levels of one or more genes in a first and second sample wherein a change in the level of expression of one or more genes or gene products in the first biological sample compared to the level of expression of one or more genes or gene products in the second biological sample is diagnostic of breast cancer and the Group III-IV methods comprise analyzing the level of expression between one or more genes and/or gene products in a cell prior and subsequent to treatment with a compound wherein the variation in the expression level of the gene and/or gene product is indicative of drug efficacy. Moreover the Group I-II and Group III-IV inventions are not obvious variants because, for example, expression profiles indicative of breast cancer such as in the Group I-II inventions are not necessarily indicative of or capable of identifying compounds useful for the treatment of breast cancer as in the Group III-IV inventions. Therefore, the methods are not obvious variants over each other.

Art Unit: 1636

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions V and VI are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions of Groups V and VI do not overlap in scope because the Group V invention is comprised of polynucleotides capable of hybridizing to other polynucleotides, and the Group VI invention is comprised of polypeptides. The inventions of Groups V and VI are not obvious variants due to their completely different structures and chemical properties: Group V comprises nucleic acids comprised of nucleotides, and the Group VI

Art Unit: 1636

invention comprises polypeptides comprised of amino acid residues. The Group V and VI inventions also have a completely different design and mode of operation; for example, the Group V array has multiple polynucleotides immobilized on a solid surface useful for detection of gene expression while the Group VI invention has multiple polypeptides, which are detected via protein-protein interactions.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions I & III and Invention V are related as processes and products for their practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be

Art Unit: 1636

practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the processes of Groups I & III as claimed can be practiced by utilizing any combination of polynucleotides present on any of the different arrays encompassed by the Group V invention. For example, the Group I invention could be practiced with an array comprising SEQ ID NOs: 1-10 or SEQ ID NOs: 11-20.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II & IV and Invention VI are related as processes and products for their practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be

Art Unit: 1636

used to practice another and materially different process.

(MPEP § 806.05(e)). In this case the processes of Groups II & IV as claimed can be practiced by utilizing any combination of polypeptides present on any of the different arrays encompassed by the Group VI invention. For example, the Group II invention could be practiced with an array comprising SEQ ID NOs: 254-264 or SEQ ID NOs: 265-274.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I & III and Invention VI are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Groups I and III utilize hybridization of nucleic acids to monitor gene expression and the Group VI invention is comprised

Art Unit: 1636

of polypeptides not disclosed as capable of binding to nucleic acids for assaying gene expression. Thus, the Group I and III and Group VI inventions have different modes of operation and designs.

Inventions II & IV and Invention V are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Groups II and IV utilize polypeptides to monitor gene expression and the Group V invention is comprised of polynucleotides not disclosed as capable of determining polypeptide expression. Thus, the Group I and III and Group VI inventions have different modes of operation and designs.

Claims 1 and 4 link inventions I and II. Claims 7 and 10 link inventions III and IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 4, 7 and 10. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the

Art Unit: 1636

limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of

Art Unit: 1636

an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Art Unit: 1636

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy

Art Unit: 1636

should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday

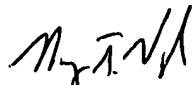
Art Unit: 1636

through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

June 27, 2006


NANCY VOGEL
PRIMARY EXAMINER